Message Text

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PAGE 01 STATE 176800

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ORIGIN HEW-06

INFO OCT-01 ARA-10 NEA-10 ISO-00 OES-06 EB-07 COME-00 /040 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.: PFF
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/OIH: MACODDING
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P 162011Z JUL 76
FM SECSTATE WASHDC
TO AMEMBASSY CAIRO PRIORITY
AMEMBASSY SAN SALVADOR
AMEMBASSY BRIDGETOWN
AMEMBASSY JIDDA

UNCLAS STATE 176800

E.O. 11652: N/A

TAGS: 0GEN, ETRD, EIND, TBIO, EG, ES, GJ, SA

SUBJECT: FDA ADVISORY - RECALL T-119-6 - LEAKING CONTAINERS IN DIAGNOSTIC TEST KIT.

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED: IN VITRO DIAGNOSTIC TEST KIT, BILIRUBIN 50 TEST. EACH PACKAGE CONTAINS THE FOLLOWING:

A. REAGENT VIAL - INGREDIENT SODIUM NITRATE 0.50 MG.

B. MIXI-TUBE NO. 1 - SULFANILIC ACID 2.00 MG AND HYDRO-CHLORIC ACID 0.03 ML.

C. MIXI-TUBE NO. 2 - METHANOL 2.00 ML.

D. CALIBRATION CHARTS AND INSTRUCTIONS

2. PRODUCT IDENTIFICATION: BILIRUBIN 50 TESTS LABELED BILIRUBIN TESTS XXX FOR INVITRO DIAGNOSTIC USE CAUTION UNCLASSIFIED

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XXX FIRST AID XXX XXX MANUFACTURED BY SEROSONIC LABS.,

INC., A SUBSIDIARY OF MALLINCKRODT, INC., 1644 LOCUST AVE., BOHEMIA, N.Y., 11716.

3. LOT NOS.: 760209-STAMPED ON LABEL. SEROSONIC'S CATALOG NO. G5030-50 STAMPED ON LABEL. EXPIRATION DATE FEBRUARY 1977.

4. MANUFACTURER/RECALLING FIRM: THE MANUFACTURER, RECALLING FIRM AND RESPONSIBLE FIRM IS SERSONIC LABS., INC., A SUBSIDIARY OF MALLINCKRODT, INC., 1644 LOCUST AVE., BOHEMIA, N.Y., 11716. CF NO. 24-311, DTA 2-3, CTY 103. - -

5. REASON FOR ADIVSORY (RECALL): DURING A ROUTINE IN-HOUSE INSPECTION, ONE MONTH AFTER DISTRIBUTION, THE FIRM DISCOVERED LOW LEVELS OF METHANOL IN MIXI TUBE NO. 2 (BELOW THE 2 ML REQUIRED FOR THE TEST). THE LEAKAGE WAS DUE TO SLIGHT IMPERFECTIONS IN THE MIXI TUBE CAPS. THE FIRM FOUND IMPERFECTIONS IN APPROXIMATELY 27 OF MIXI TUBES. THE IMPERFECTION WAS CAUSED BY A DEFECT IN THE MIXI TUBE CAP MOLD. INTERNATIONAL CONSIGNEES WERE CONTACTED ON MARCH 4, 1976. THE FIRM REQUESTED THAT EACH ACCOUNT RETURN THE CALIBRATION CHARTS ONLY. REMAINDER OF THE BILIRUBIN TEST KITS WERE TO BE DESTROYED BY THE CONSIGNEES.

6. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED INSTRUCTIONS FROM THE FIRM IN THEIR RECALL LETTER OF MARCH 4, 1976. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING THIS RECALL SHOULD BE DIRECTED TO THE FIRM.

7. FOREIGN CONSIGNEES AS FOLLOWS:

A. DR. AHMED FOUAD
FLAT 18
5 SHERIF PACHA STREET
CAIRO, EGYPT

B. DRUGUERIA PRO-MEDICI
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APARTADO POSTAL NO. 1503
SAN SALVADOR, EL SALVADOR

C. GOVERNMENT HOSPITAL LAB
GENERAL HOSPITAL
ST. GEORGES
GRENADA, WEST INDIES

D. DR. BAGHAFFAR
P.O. BOX 20
JIDDA, SAUDI ARABIA KISSINGER

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Decaption Date: 01 JAN 1960
Decaption Note:
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Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
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Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Drafter: JRWEINROTH, M.D.: PFF
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Executive Order: N/A
Errors: N/A
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TAGS: ETRD, EIND, TBIO, EG, ES, GJ, SA
To: CAIRO
MULTIPLE
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